510(k) Summary, Elecsys Estradiol III CalSet

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Name

Proprietary name: Elecsys Estradiol III CalSet

Common name: Estradiol III CalSet

Classification: 21 CFR 862.1150, Calibrator, Secondary

Product Code: JIT

Establishment Registration

For the Estradiol III CalSet, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany, is 9610126 and for Penzberg, Germany, is 9610529. The establishment registration number for Roche Diagnostics United States is 1823260.

Classification

FDA has classified the product as a Class II device.

Product Name	Panel	Product Code	Classification Name	Regulation Citation
Estradiol III CalSet	Clinical Chemistry	JIT	Calibrator, Secondary	21 CFR 862.1150

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510(k) Summary, Elecsys Estradiol III CalSet, *continued*

Device Description

Elecsys Estradiol III CalSet:

- The Elecsys Estradiol III CalSet is a lyophilized product consisting of synthetic Estradiol in a human serum matrix. It has been standardized against ID-GC/MS (isotope dilution gas chromatography mass spectrometry).

Intended use

Elecsys Estradiol III CalSet:

- Estradiol III CalSet is used for calibrating the quantitative Elecsys Estradiol III assay on the Elecsys and **cobas e** immunoassay analyzers.

Predicate device

The Elecsys Estradiol III CalSet is substantially equivalent to the predicate device, Elecsys Estradiol II CalSet II (K992981).

Substantial Equivalence Comparison

The following tables compare the Elecsys Estradiol III CalSet with the predicate device.

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Comparison Table

The table below compares Elecsys Estradiol III CalSet with the predicate device, Elecsys Estradiol II CalSet II (K992981).

The change in the new product was a shift in the Cal 2 target value.

Table

Characteristic	**Elecsys Estradiol III CalSet (Candidate)**	**Elecsys Estradiol II CalSet II (K992981)**
Intended Use	Estradiol III CalSet is used for calibrating the quantitative Elecsys Estradiol III assay on the Elecsys and **cobas e** immunoassay analyzers.	Estradiol II CalSet II is used for calibrating the quantitative Elecsys Estradiol II assay on the Elecsys and **cobas e** immunoassay analyzers.
Analyte	Estradiol (synthetic)	Same
Matrix	Human serum matrix	Same
Levels	Two	Same
Target Ranges	Cal 1: 20 pg/mL Cal 2: 2000 pg/mL	Cal 1: 20 pg/mL Cal 2: 3000 pg/mL
Format	Lyophilized	Same
Handling	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the foam formation. Transfer aliquots of the reconstituted calibrators into empty labeled snap-cap bottles (CalSet Vials). Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20°C. Perform only one calibration procedure per aliquot.	Same.

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Table *continued*

Characteristic	Elecsys Estradiol III CalSet (Candidate)	Elecsys Estradiol II CalSet II (K992981)
Stability	Unopened: • Store at 2-8°C until expiration date Opened: • 2-8°C: 24 hours • 20-25°C: 5 hours on Elecsys 2010/**cobas e** 411; use only once on MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers • -20°C: 31 days (freeze only once)	Unopened: • Store at 2-8°C until expiration date Opened: • 2-8°C: 24 hours • 20-25°C: use only once • -20°C: 3 month

Traceability

The Elecsys Estradiol III CalSet was standardized against ID-GC/MS (isotope dilution gas chromatography mass spectrometry).

Evaluations Summary

The Elecsys Estradiol III CalSet was evaluated for value assignment, reconstitution and stability.

CalSet Value Assignment

Value assignment testing was conducted and passed pre-defined acceptance criteria. The target values for the two levels of the Estradiol III CalSet kit are chosen to obtain the best fit with the Master Calibration Curve, together with the Rodbard curve parameters encoded in the reagent barcode. For each Elecsys Estradiol III CalSet lot manufactured, the calibrators are run in duplicate on at least three (3) Elecsys 2010/**cobas e** 411 analyzers and at least three (3) **cobas e** 601/MODULAR ANALYTICS E170 analyzers with all Estradiol III reagent lots available. The assigned value of each calibrator is defined as the mean value obtained over at least six (6) runs on at least three (3) analyzers) of the respective calibrator.

Measurement values for PreciControl Universal (Level 1 & 2), a multi-analyte control recommended for use to monitor accuracy and precision of specified analytes, are read from the calibration curves generated. The pre-defined acceptance criteria for PreciControl Universal have to be met to release the Assigned Values for Estradiol III CalSet.

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Stability Studies

Three studies were performed in order to verify the stability claims for the Estradiol III CalSet. Stability studies after reconstitution and an accelerated stability study were completed on the **cobas e** 411. Additionally, a real-time stability study is planned.

Study 1. Stability at 2-8°C, -20°C, in open vial and freeze/thaw cycles (after reconstitution):

The on-test materials were reconstituted and stored closed for 73 hours at 2 to 8°C, and for 32 days at -20°C and for 7 hours at 20 to 25°C in open vial prior to testing. In addition, the stability of the Estradiol III CalSet for two (2) freeze/thaw cycles was evaluated.

The on-test and reference materials were tested in duplicate and the recovery was calculated as percent of the reference value.

The acceptance criterion was 95 to 105 % signal recovery of the reference material value. The reference material was a freshly reconstituted set of Estradiol III CalSet.

Study 2. Accelerated Stability:

The on-test material was stored lyophilized (as supplied to the user) at 35°C for 3 weeks. The reference material was a freshly reconstituted set of Estradiol III CalSet (stored at 2 to 8°C). After 3 weeks, the on-test and reference materials were tested in duplicate. The on-test recovery was calculated as a percent of the reference value. One Estradiol III CalSet lot was evaluated in duplicate.

The acceptance criterion was 95 to 105 % recovery of the reference material value.

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Stability Studies, *continued*

Study 3. Real-Time Stability:

In addition, real-time stability is being evaluated as follows:
In the on-going real-time stability study, the Estradiol III CalSet test material is stored at 2-8°C. The CalSets are tested in duplicate at specified intervals over the shelf life of the device up to the planned shelf life plus one month (19 months).

Real-time stability is calculated based on the recovery of signal of stressed calibrator (stored at 2-8°C) vs. unstressed calibrator (stored at -20°C). At the specified intervals over the shelf life, the mean value of the stressed calibrator was calculated as percent recovery of the unstressed value (each tested in duplicates at the same time point).

The acceptance criterion for Estradiol III Calibrator 1 and 2 is recovery of 95-105 % of the reference value.

The testing will continue with this stability protocol until data to support a claim of 18 months are achieved.

Conclusion

We trust that the information provided in this Premarket Notification (510(k)) will support a determination of substantial equivalence for the Elecsys Estradiol III CalSet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2014

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPAL
9115 HAGUE ROAD
INDIANAPOLIS IN 46250-0416

Re: K142021
Trade/Device Name: Elecsys Estradiol III CalSet
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: July 24, 2014
Received: July 25, 2014

Dear Ms. Kelli Turner:

This letter corrects our substantially equivalent letter of August 12, 2014. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142021

Device Name
Elecsys Estradiol III CalSet

Indications for Use *(Describe)*
Estradiol III CalSet is used for calibrating the quantitative Elecsys Estradiol III assay on the Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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